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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,555	09/22/2000	Ypke Vincentius Johannes Maria van Oosterhout	4541US	2631

24247 7590 12/11/2001

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	(0)

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/668,555	VAN OOOSTERHOUT ET AL.
Examiner	Ron Schwadron, Ph.D.	Art Unit
		1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_ .

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-13,15 and 18-23 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 1-13,15,18-23 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of: EP 98200917.7  
1.  Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ . 6) Other: \_\_\_\_ .

Serial No. 09/668555  
Art Unit 1644

1. Claims 1-13,15,18-23 are under consideration. Claims 14,16,17 have been cancelled. Claims 1-13,15 have been amended. Claims 18-23 have been added.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

A) Non-initialed and/or non-dated alterations have been made to the oath or declaration (non-initialed changes were made to the application number of the cited EP). See 37 CFR 1.52(c).

B) It states that is the specification for 09/668555 and for PCT NL/00156. Said application as filed is the specification of 09/668555 and a continuation of PCT NL/00156.

3. The van Oosterhout document cited on the instant IDS has not been considered because it was supplied without citation information (no date of publication, journal, etc.).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8,10-13,15,18-23 are rejected under 35 U.S.C. 102(b) or (a) as being anticipated by van Oosterhout et al.

Applicant needs to supply the date that the instant reference was published in order to determine if the instant rejection should be made under 35 U.S.C. 102(b) or (a).

The reference was the work of at least one of the inventors of the instant application so this information should be readily available to applicant.

van Oosterhout et al. teach use of a pharmaceutical composition containing antiCD3 antibody/deglycosylated ricin A and antiCD3 antibody/deglycosylated ricin A to treat GVHD. SPV-T3a contains a gamma2B IgG antibody (specification, page 9 discloses that said antibody is of said isotype). The pharmaceutical composition taught by van Oosterhout et al. has the dosage recited in claims 11 and 12, because said recited dosage is based on the subject's size and the subject could be of any size.

6. Claims 1-5,7-13,15,18,19,21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Scannon et al. (WO 89/06967)

Scannon et al. teach use of a pharmaceutical composition containing antiCD3 antibody/ ricin A and antiCD7 antibody/ ricin A to treat GVHD (see page 4, first paragraph, page 6, first paragraph, page 12, page 13). Scannon et al. teach that the immunotoxin can be prepared by chemical linkage (see page 14 and 15). Scannon et al. teach that the composition can contain antibody immunotoxins against the T cell markers CD3, CD7, CD5 (page 4, first paragraph). The pharmaceutical composition taught by Scannon et al. (see page 10, last paragraph) has the dosage recited in claims 11 and 12, because said recited dosage is based on the subject's size and the subject could be of any size. As per the definition of "derivative" on page 5 of the specification, a derivative of an IgG2B antibody would be any antibody of any isotype which binds CD3 or CD7.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the

various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-13,15,18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scannon et al. (WO 89/06967) in view of Thorpe et al. (US 6,261,535).

Scannon et al. teach use of a pharmaceutical composition containing antiCD3 antibody/ ricin A and antiCD7 antibody/ ricin A to treat GVHD (see page 4, first paragraph, page 6, first paragraph, page 12, page 13). Scannon et al. teach that the immunotoxin can be prepared by chemical linkage (see page 14 and 15). Scannon et al. teach that the composition can contain antibody immunotoxins against the T cell markers CD3, CD7, CD5 (page 4, first paragraph). The pharmaceutical composition taught by Scannon et al. (see page 10, last paragraph) has the dosage recited in claims 11 and 12, because said recited dosage is based on the subject's size and the subject could be of any size. As per the definition of "derivative" on page 5 of the specification, a derivative of an IgG2B antibody would be any antibody of any isotype which binds CD3 or CD7. Scannon et al. do not teach the claimed invention which uses deglycosylated ricin A. Thorpe et al. teach use of deglycosylated ricin A in immunotoxins (see column 2, second paragraph). Thorpe et al. teach that use of deglycosylated ricin A in immunotoxins results in decreased hepatotoxicity (see column 2, second paragraph). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Scannon et al. teach the claimed invention except for use of deglycosylated ricin A while Thorpe et al. teach use of deglycosylated ricin A and that use of deglycosylated ricin A in immunotoxins results in decreased hepatotoxicity (see column 2, second paragraph).

9. No claims are allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1600

Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644  
December 10, 2001